K080071

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

FEB - 7 2008

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the SIDEKICK™ Rail Fixator System.

Submitted By:	Wright Medical Technology, Inc.
Date:	December 26, 2007
Contact Person:	Peggy S. Rivers Regulatory Affairs Specialist
Proprietary Name:	SIDEKICK™ Rail Fixator System
Common Name:	External Fixation System
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories -Class II per 21 CFR section 888.3030
Device Product Code and Panel Code:	Orthopedics/87/KTT

DEVICE INFORMATION

A. INTENDED USES/ INDICATIONS

The SIDEKICK™ Rail Fixator System is indicated for stabilizing various fractures including open and comminuted fractures, infected non-unions, fractures with length discrepancies, fusions and corrective osteotomies of the metacarpal, metatarsal, ulnar, and calcaneal bones.

B. DEVICE DESCRIPTION

The SIDEKICK™ Rail Fixator System is a stable solution for fractures and for lengthening of small bones. The system allows precise, controlled compression/distraction and early weight bearing. The articulation pin clamps allow adjustment around three axes and linear translation so that it can be used for comminuted intra-articular fractures, or arthrodesis of the foot or hand.

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C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indications for use of the SIDEKICK™ Rail Fixator System are identical to the predicate device. The design features and materials of the subject device are substantially equivalent to those of the predicate device. The substantial equivalence information, materials information, and analysis data provided within this Premarket Notification adequately supports the safety and effectiveness of the SIDEKICK™ Rail Fixator system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2008

Wright Medical Technology, INC
% Ms. Peggy S. Rivers
Regulatory Affairs Specialist
5677 Airline Road
Arlington, TN 38002

Re: K080071
Trade/Device Name: Sidekick™ Rail Fixator System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: January 9, 2008
Received: January 11, 2008

Dear Ms. Rivers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080071

Indications for Use

510(k) Number (if known):

Device Name: SIDEKICK™ Rail Fixator System

Indications For Use:

The SIDEKICK™ Rail Fixation System is indicated for stabilizing various fractures including open an/or comminuted fractures, infected non-unions, fractures with length discrepancies, fusions and corrective osteotomies of the metacarpal, metatarsal, ulnar and calcaneal bones.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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